



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 501

[Docket No. FDA-2013-D-1088]

Guidance for Industry #223: Small Entity Compliance Guide--Declaring Color Additives in Animal Foods; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry #223 entitled "Small Entity Compliance Guide--Declaring Color Additives in Animal Foods." This small entity compliance guide (SECG) aids industry in complying with the requirements of the final rule that published in the Federal Register of November 17, 2011. FDA issued the regulation in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act). Specifically, FDA amended its regulations regarding the declaration of certified color additives on the labels of animal food including animal feeds and pet foods.

DATES: The guidance is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written comments on the SECG at any time.

ADDRESSES: Submit requests for single copies of the SECG to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing

your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the SECG.

Submit electronic comments on the SECG to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Charlotte Conway, Center for Veterinary Medicine (HFV-228), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-8649; email: charlotte.conway@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of an SECG entitled "Small Entity Compliance Guide--Declaring Color Additives in Animal Foods." This SECG aids industry in complying with the requirements of the final rule published in the Federal Register of November 17, 2011 (76 FR 71248).

FDA has prepared this SECG in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121). This document is intended to provide guidance to small businesses on the requirements of the final rule, which implements a portion of the 1990 amendments. The 1990 amendments, among other things, provided for the declaration of certified color additives on the labels of human and animal food, including animal feeds and pet foods. The 1990 amendments also provided for the listing on food labels of the common or usual names of all color additives required to be certified by FDA. This regulation deals with the requirements associated with animal food only.

Before passage of the 1990 amendments, the FD&C Act provided that colorings could be declared collectively on food product labels using the term "colorings." The 2011 regulation requires that certified color additives be declared on labeling of animal food by their common or usual name, but color additives exempt from certification (e.g., caramel, paprika, and beet juice) may still be declared collectively. The rule makes these animal food regulations consistent with the regulations regarding the declaration of certified color additives on the labels of human food. The rule also suggests appropriate terminology for the declaration of noncertified color additives on the labels of animal food.

II. Significance of Guidance

FDA is issuing this SECG as a level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This SECG refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501-3520.) The collections of information in the regulation "Animal Food Labeling; Declaration of Certifiable Color Additives" (21 CFR 501.22(k)(1) and (2)) have been approved under OMB control number 0910-0721.

IV. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

V. Electronic Access

Persons with access to the Internet may obtain the SECG at either <http://www.fda.gov/cvm> or <http://www.regulations.gov>.

Dated: September 24, 2013.

Leslie Kux,

Assistant Commissioner for Policy.